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Proposed Regulation Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation	12 VAC 5-230 Amend 12 VAC 5-240 through 360 Repeal
Regulation title	Certificate of Public Need State Medical Facilities Plan
Action title	Promulgation of 12 VAC 5-230 Repeal of 12 VAC 5-240 through 360
Document preparation date	May 3, 2004

This information is required for executive review (www.townhall.state.va.us/dpbpages/apaintro.htm#execreview) and the Virginia Registrar of Regulations (legis.state.va.us/codecomm/register/regindex.htm), pursuant to the Virginia Administrative Process Act (www.townhall.state.va.us/dpbpages/dpb_apa.htm), Executive Orders 21 (2002) and 58 (1999) (www.governor.state.va.us/Press_Policy/Executive_Orders/EOHome.html), and the *Virginia Register Form, Style and Procedure Manual* (http://legis.state.va.us/codecomm/register/download/styl8_95.rtf).

Brief summary

*Please provide a brief summary of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation. Do **not** state each provision or amendment or restate the purpose and intent of the regulation.*

Except for changes required by legislative mandate, the State Medical Facilities Plan (SMFP) has not been reviewed and updated since it was first promulgated in 1993. The SMFP is one of twenty criteria used to determine public need in eleven categories of medical care facilities subject to the Certificate of Public Need (COPN) law. The goal of the revision project is to update the criteria and standards to reflect current national and health care industry standards, remove archaic language and ambiguities, and consolidate all portions of the SMFP into one comprehensive document. Because of the consolidation of the current 14 separate sections into one comprehensive document, 12 VAC 5-240 through 12 VAC 5-360 are being repealed as 12 VAC 5-230 is promulgated.

Basis

Please identify the state and/or federal source of legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly bill and chapter numbers, if applicable, and (2) promulgating entity, i.e., the agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

The State Medical Facilities Plan (SMFP) is promulgated by the Center for Quality Health Care Services and Consumer Protection of the Virginia Department of Health, for the Board of Health, under the authority of §§ 32.1-102.1 through 32.1-102.3 of the *Code of Virginia*. Section 32.1-102.1 defines the SMFP as a planning document adopted by the Board of Health (Board); 32.1-102.2 mandates that the Board promulgate regulations to implement Virginia's Medical Care Facilities Certificate of Public Need (COPN) law in which, as set out in § 32.1-102.3 of the Code, any decision to issue or approve the issuance of a certificate shall be consistent with the most recent applicable provision of the State Medical Facilities Plan." Existence of the SMFP, therefore, is mandated.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

The Virginia Medical Care Facilities Certificate of Public Need law requires owners or sponsors of medical care facility projects to secure a COPN from the State Health Commissioner prior to initiating such projects. The SMFP is essential to the implementation of the COPN program as it provides the criteria and standards for the full range of capital expenditure project categories that require review, including general acute care services, perinatal services, diagnostic imaging services, cardiac services, general surgical services, organ transplantation services, medical rehabilitation services, psychiatric/substance abuse services, mental retardation services, lithotripsy services, miscellaneous capital expenditures and nursing facility services. The SMFP provides applicants and reviewing agencies with a framework for examining the need for these projects.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (Provide more detail about these changes in the "Detail of changes" section.)

The Code specifies that the SMFP shall include, but is not limited to: (i) methodologies for projecting need for medical care facility beds and services, (ii) statistical information on the availability of medical care facilities and services; and (iii) procedures, criteria and standards for the review of applications for projects or medical care facilities and services. Many standards were not measurable, or were reflective of licensing standards, and not relevant to the COPN application review process. Much of the language was archaic and subject to interpretation. Therefore, all standards were tested for measurability and were modified or deleted as appropriate. Duplicative and repetitive standards were combined and relocated to six new sections in the “Definitions and General Information” section of the document.

Issues

Please identify the issues associated with the proposed regulatory action, including:

- 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;*
 - 2) the primary advantages and disadvantages to the agency or the Commonwealth; and*
 - 3) other pertinent matters of interest to the regulated community, government officials, and the public.*
- If there are no disadvantages to the public or the Commonwealth, please indicate.*

Since the SMFP is such an integral part of the COPN process, no discussion of the SMFP can be conducted without mentioning the COPN program. The COPN law states the program objectives: (i) promote comprehensive health planning to meet the needs of the public; (ii) promote highest quality of care at the lowest price; (iii) avoid unnecessary duplication of medical care facilities; (iv) provide an orderly procedure for resolving questions concerning the need to construct or modify medical care facilities. In other words, the program seeks to contain health care costs while ensuring financial viability and access to health care for all Virginians at a reasonable cost. The COPN program has long been a controversial feature of government efforts to contain health care costs. However, lacking a consensus on what might work better, Virginia, like 36 other states, has chosen to maintain its COPN program. That decision, however, does not prevent the Department from taking steps to address and alleviate, where possible, some of the on-going controversy regarding the COPN program. There are two issues surrounding the COPN program and subsequently the SMFP: (i) the perception that the COPN program ensures “quality” health care services, and (ii) the program has become a guarantor of “franchise” providers, i.e., those providers already holding a COPN, making it difficult for new health care providers to enter the health care market in Virginia.

Over time, the COPN program has inherited a reputation as a program that monitors and ensures quality health care services to Virginia’s citizens. However, only legislatively mandated licensure programs can ensure quality health care services. The COPN “quality” misperception results from some of the criteria in the current SMFP. Therefore, one of the objectives of the SMFP revision project was to remove references to provider actions that would occur well *after* the granting of a COPN. In actuality, the COPN law does not provide enforcement of the individual sections of the SMFP. Rather, a COPN can only be revoked when: (i) substantial and continuing progress towards project completion has not been made; (ii) the maximum capital expenditure is exceeded, (iii) the applicant has willfully or recklessly misrepresented intentions or facts to obtain a COPN, or (iv) a continuous care retirement community has failed to establish

a nursing facility as required by law. The COPN law does not permit inspection after issuing the COPN, the only method in which “quality” failures can be identified. The SMFP can only impact quality through the service volume standards. It is well known in the health care industry, that the volume of service provision results in better outcomes and survival rates for patients and services recipients. Therefore, the service volume standards were carefully reviewed and adjusted to meet nationally accepted practices.

Another objective of the revision project was to ensure the resultant document is clearly written and understandable. Much work was necessary in order to bring the SMFP up to currently accepted standards and practice. The approach used was to strive for simplicity, avoid being burdensome, while meeting the requirements of the law. The Department was careful to replace archaic language, which was ambiguous and subject to interpretation, with common vernacular to ensure the document readability.

As a result of the two objectives, the Department considers the proposed SMFP more user-friendly and provides more opportunity for new facility and services providers to obtain a COPN. Therefore, the proposed SMFP is advantageous for Virginia’s citizens as well as the health care industry as it has the potential for allowing more competition.

In addition, the Department hopes the new document successfully addresses one aspect of the COPN controversy: the general restrictiveness of the program or conversely, the perception that COPN restricts fair market competition. By carefully reviewing all service volume criteria, making appropriate adjustments, and removing criterion that is outdated or not applicable to the application review process, the Department hopes to have successfully removed some of the more objectionable hurdles to obtaining a COPN. Therefore, there is no disadvantage to the public or the Commonwealth as a result of the proposed revisions.

Small businesses or organizations contracting with COPN applicants for development services would be affected by the revised regulation. This would include consultants and lawyers hired to help guide applicants through the COPN process.

Financial impact

Please identify the anticipated financial impact of the proposed regulation and at a minimum provide the following information:

Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source / fund detail, and (b) a delineation of one-time versus on-going expenditures	The costs of implementing the revised SMFP are minimal, as no changes have been made to the operation or application review functions required for issuing a certificate of public need.
Projected cost of the regulation on localities	None, unless the locality chooses to own or operate a medical care facility requiring a COPN. There are 5 nursing facilities and 5 hospitals owned or operated by local governments.
Description of the individuals, businesses or other entities likely to be affected by the regulation	Nursing facilities, hospitals, other medical facility providers, rural citizens, and indigent patients.
Agency’s best estimate of the number of such entities that will be affected	Approximately 100 applications are received each year.
Projected cost of the regulation for affected	None – however, there are costs to apply for the

individuals, businesses, or other entities	Certificate of Public Need
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Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action.

The Department is required to regulate the medical care facility projects defined in § 32.1-102.1 of the Code. The SMFP is necessary to carry out the mandate of the COPN law.

Public comment

Please summarize all comments received during the public comment period following the publication of the NOIRA, and provide the agency response.

Commenter	Comment	Agency response
Margaret P. King Executive Director No. VA Health Systems Agency, Inc. (NWWHSA)	The NWWHSA Plan Development Committee and the full Board of Directors considered the recently issued Notice of Intended Regulatory Action on the State Medical Facilities Plan (SMFP). Both the Committee and the full Board, by unanimous vote, opposed any formal regulatory action on amendments to the SMFP at this time.	VDH is aware that the Health Systems Agencies (HSAs) generally oppose efforts to revise the SMFP until some non-specific future date. However, the current SMFP no longer reflects appropriate volume standards because of changes in use of technology. In addition, many of the standards are not measurable or verifiable during the project review process. During three successive periodic regulatory reviews, the entire SMFP was identified as needing consolidation and updating to facilitate its use. When convening the project advisory committee, the HSAs enjoyed disproportionate representation on the committee. Specifically, the HSAs had 3 representatives involved in the committee, yet there are only five HSAs. Therefore, VDH does not agree with the HSAs that the project should be delayed.
Karen L. Cameron, CHE Executive Director/CEO Central Virginia Health Planning Agency, Inc. (CVHPA)	The CVHPA staff, Board of Directors, and Capital Area Health Advisory Council have discussed the Department's recent notice of intended regulatory action. The CVPA strongly recommends that this action be deferred.	
Dean Montgomery Executive Director Health Systems Agency of Northern Virginia (HSANV)	The HSANV Board of Directors discussed the Department's recent notice of intended regulatory action that would initiate the rulemaking process to promulgate a revised [SMFP]. The Board requests that this action be deferred.	
Shelden M. Retchin, M.D. M.S.P.H. Senior Executive Vice President and CEO, VCU Health System	Provided a position statement from the VCU Health System regarding state Department of Health decision on the addition of liver transplant programs in the Commonwealth.	

		transplant volumes had in fact increased from 12 to 20 effective February 2003. In addition, the proposed liver transplant volume is set to increase, by 1, as a result of the recommendations of the SMFP advisory committee. Dr. Retchin was satisfied with our response.
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Impact on family

Please assess the impact of the proposed regulatory action on the institution of the family and family stability.

There is not direct impact on families as a result of revising the SMFP

Detail of changes

Please detail all changes that are being proposed and the consequences of the proposed changes. Detail all new provisions and/or all changes to existing sections.

If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all changes between the pre-emergency regulation and the proposed regulation, and (2) only changes made since the publication of the emergency regulation.

There is no significance to the placement of the sections in the proposed SMFP. Section placement is determined by the order in which the advisory committee reviewed the applicable section. For example, the committee reviewed the standards pertaining to “Diagnostic Imaging” first, so those sections moved to the front of the SMFP. Likewise, the committee reviewed “Perinatal Services” last; hence that section can be found last in the proposed SMFP.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
230-10 240-10 250-10 260-10 270-10 280-10 290-10 300-10 310-10 320-10 330-10	230-10	Definitions	All definitions were combined into one section at the front of the document. Obsolete or non-related definitions were removed, new definitions added to aid clarification, and other definitions revised to reflect actual medical definitions.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
340-10 360-10			
230-20 State Medical Facilities Plan	230-20	Preface	Revise to explain role and responsibilities of the Department and the Division of COPN
230-30	230-30	Guiding Principles	Text was edited for proper language usage.
	230-40	N/A	Section contains “general application filing criteria;” the first of the new general criterion sections to reduce redundancy in the document.
	230-50	N/A	Section addresses “project costs;” one of the new general criterion sections developed to consolidate redundancy in related standards throughout the current SMFP.
	230-60	N/A	Section addresses “preferences” to granting a COPN; this section was developed to consolidate and decrease redundancy of all preferences scattered throughout the current SMFP.
	230-70	N/A	Section addresses “emerging technologies” to allow for consideration of technical advances in the regulated technologies and requires registration of new technologies. This is an enhancement to the SMFP.
	230-80	N/A	Section addresses “institutional need” in granting a COPN; this is an enhancement to the current SMFP requested by providers.
	230-90	N/A	Section addresses “compliance with the terms of a condition” by providing the standards for providers regarding indigent care services agreed to as a condition for granting a COPN. This is an enhancement to the SMFP.
240-20 General Acute Care Services	230-440, 60	Accessibility	Section moved. Standard addressing indigent care was moved to section 60 – Preferences.
240-30	230-450	Availability	Section revised to provide measurable criteria; language updated and

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
			ambiguities removed.
240-40	N/A	Continuity	Standards not verifiable or enforceable during the project review process; Addressed in facility licensure criteria, 12 VAC 5-410.
240-50	230-50, 60	Cost	All “cost” sections were duplicative and redundant; sections were combined to facilitate use of the SMFP. Relevant sections are “costs” and “preferences.”
240-60	N/A	Quality; accreditation and compliance with chapters.	Criteria not verifiable or enforceable during project review process. Section deleted.
250-20 Perinatal Services	N/A	Acceptability	Philosophic statement. Criteria not verifiable or enforceable during project review process. Section deleted.
250-30	230-670	Accessibility	Section modified to better reflect expectations
250-40	230-680	Availability	Section modified to better reflect expectations
250-50	230-690	Continuity	Revised to remove outdated references and licensure requirements; section revised to contain measurable standards during the project review process.
250-60	230-50, 60	Cost	All “cost” sections were duplicative and redundant; sections were combined to facilitate use of the SMFP. Relevant concepts included in “costs” and “preferences” sections
250-70	N/A	Quality standards; data collection.	Section deleted, references were archaic and not measurable during the project review process.
250-80	230-700	Accessibility, travel time; payment	Section revised to remove outdated references.
250-90	230-710	Availability; service capacity	Section revised to reflect current neonatal capacity.
250-100	230-720	Neonatal services; continuity; agreement; follow-up care.	Section revised, references were archaic and not measurable or enforceable during the project review process.
250-110	230-50, 60	Cost; regionalization; levels of care.	All “cost” sections were duplicative and redundant; sections were combined to facilitate use of the SMFP. Relevant

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
			concept included in “costs” and “preferences” sections.
250-120	N/A	Quality	Philosophical statements. Section deleted, references were archaic and not measurable during the project review process.
260-20 Cardiac Services	N/A	Acceptability	Philosophical statement. Section deleted, references were archaic and not measurable during the project review process.
260-30	230-360, 60	Accessibility; financial considerations.	Section revised, concepts realigned to facilitate use of the SMFP.
260-40	230-370	Availability; need for new services; alternatives	Section revised to provide measurable criteria; language updated and ambiguities removed.
260-50	N/A	Continuity; coordination	Philosophical statement. Standards not verifiable or enforceable during the project review process; addressed in facility licensure criteria, 12 VAC 5-410.
260-60	230-50, 60	Cost; alternatives	All “cost” sections were duplicative and redundant; sections were combined to facilitate use of the SMFP. Relevant concepts included in “costs” and “preferences” sections
260-70	230-380	Quality; staffing patient care and support services	Philosophical statement. Section revised to address staffing; other section criteria not measurable or verifiable during the project review process and were deleted.
260-80	230-80	Acceptability; consumer participation	Philosophical statement. Section deleted – criteria not relevant to COPN and not measurable or verifiable during the project review process.
260-90	230-390	Accessibility; travel time; financial considerations	Philosophical statement removed. Remaining standards combine into one standard.
260-100	230-400	Availability; need for the new service; alternatives	Section revised to provide measurable criteria; language updated and ambiguities removed.
260-110	N/A	Continuity; coordination	Section deleted, criteria not measurable or verifiable during the project review process.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
260-120	230-50, 60	Cost; alternatives	All “cost” sections were duplicative and redundant; sections were combined to facilitate use of the SMFP. Relevant concepts included in “costs” and “preferences” sections.
260-130	230-410	Quality; staffing patient care and support services	Section revised to address staffing; other section criteria not measurable or verifiable during the project review process and were deleted.
270-20 General Surgical Services	N/A	Acceptability	Philosophical statement; not measurable or verifiable during the project review process.
270-30	230-420, 60	Accessibility; travel time; financial	Access standard revised; other standards were redundant and deleted.
270-40	230-430	Availability; need	Section revised to provide measurable criteria; language updated and ambiguities removed.
270-50	230-50, 60	Cost; charges	All “cost” sections were duplicative and redundant; sections were combined to facilitate use of the SMFP. Relevant concept included in “costs” and “preferences” sections.
270-60	N/A	Quality; accreditation/licensure	Philosophical statement, section deleted.
280-20 Organ Transplant Services	N/A	Acceptability; consumer participation	Philosophical statement and a licensure requirement; not measurable or verifiable during the project review process.
280-30	230-500	Accessibility; travel time; access to available organs	Section revised, non-measurable standard deleted.
280-40	230-510	Availability; rationalization of services; conditional approval; HCFA Medicare requirements	Philosophical statements removed; section revised; language updated and ambiguities removed.
280-50	N/A	Continuity of care; discharge planning procedures and follow-up	Section deleted; contained licensure standards that are not measurable or verifiable during the project review process.
280-60	230-50	Cost and charges	All “cost” sections were duplicative and redundant; sections were combined to facilitate use of the SMFP.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
280-70	230-520	Quality; minimum utilization; minimum survival rate; services proficiency; staffing; systems operations; support services	Survival rates were revised to reflect national standards; language was updated and ambiguities removed to facilitate use of the SMFP.
290-20 Psychiatric and Substance Abuse Treatment Services	N/A	Acceptability	Philosophical statement; criteria not measurable or verifiable during project review process.
290-30	230-610	Accessibility; travel time; financial considerations	Section revised as requested by the Department of Mental Health, Mental Retardation and Substance Abuse Services, language was updated and ambiguities removed.
290-40	230-620	Availability; treatment beds; combined need; intermediate care	Section revised as requested by the Department of Mental Health, Mental Retardation and Substance Abuse Services, language was updated and ambiguities removed.
290-50	N/A	Continuity; integration	Philosophical statement; not measurable or verifiable during the project review process.
290-60	230-50, 60	Cost and charges	All “cost” sections were duplicative and redundant; sections were combined to facilitate use of the SMFP. Relevant concept included in “costs” and “preferences” sections.
290-70	N/A	Quality; accreditation and compliance with chapters	Philosophical statement, section deleted.
300-20 Mental Retardation Services	N/A	Accessibility; financial considerations	Philosophical statement, section deleted.
300-30	230-630	Availability; need	Section revised as requested by the Department of Mental Health, Mental Retardation and Substance Abuse Services, language was updated and ambiguities removed.
300-40	230-640	Continuity, integration	Philosophical statement; not measurable or verifiable during the project review process.
300-50	N/A	Quality	Section deleted, incorporated into 230-

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
			650.
300-60	230-650	Acceptability; size, channels for consumer; participation	Section revised; language updated and ambiguities removed.
300-70	230-50, 60	Cost and Charges	All “cost” sections were duplicative and redundant; sections were combined to facilitate use of the SMFP. Relevant concept included in “costs” and “preferences” sections.
310-20 Medical Rehabilitation Services	N/A	Acceptability; channels of consumer participation	Philosophical statement, not measurable or verifiable during the project review process.
310-30	230-580, 60	Accessibility; travel time; financial considerations	Financial considerations criteria were duplicative and deleted.
310-40	230-590	Availability; need	Section revised; language updated and ambiguities removed.
310-50	N/A	Continuity; integration	Philosophical statement deleted, not measurable or verifiable during the project review process.
310-60	230-50	Cost	All “cost” sections were duplicative and redundant; sections were combined to facilitate use of the SMFP.
310-70	230-600	Quality; Staffing and services	Section revised as appropriate; non-measurable or verifiable standards were deleted.
320-20 Computed Tomography (CT)	N/A	Consumer acceptance of services offered	Philosophical statement, non-measurable or verifiable during the project review process.
320-30	230-100	Location	Section name changed.
320-40	230-60	Financial considerations; ability to pay	Section duplicative and redundant; section deleted.
320-50	230-110	Need for new service.	Section revised as appropriate; non-measurable or verifiable standards were deleted.
320-60	230-120	Expansion of existing service	Section revised as appropriate; non-measurable or verifiable standards were deleted.
320-70	N/A	Replacement of existing equipment	Replacement of equipment was repealed as a COPN project, section deleted.
320-80	N/A	Coordination of service	Philosophical statement; not measurable or verifiable during the

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
			project review process.
320-90	230-50	Cost and charges	All “cost” sections were duplicative and redundant; sections were combined to facilitate use of the SMFP. Relevant concepts included in “costs” and “preferences” sections.
320-100	230-130	Staffing	Section revised as appropriate; not measurable or verifiable standards were deleted.
320-110	230-140	Space	Section revised as appropriate; not measurable or verifiable standards were deleted.
320-120 Magnetic Resonance Imaging (MRI)	N/A	Consumer acceptance of services offered.	Philosophical statement deleted; not measurable or verifiable during the project review process.
320-130	230-150	Location	Section revised as appropriate; not measurable or verifiable standards were deleted.
320-140	230-60	Financial	Section duplicative and redundant, section deleted.
320-150	230-160	Need for new service	Section revised as appropriate; not measurable or verifiable standards were deleted.
320-160	230-160	Alternative need for new MRI service	Combined with preceding section to facilitate use of the SMFP.
320-170	230-170	Expansion of services	Section revised; language updated and ambiguities removed.
320-180	N/A	Mobile services	Section deleted as it is no longer necessary to consider mobile services separate from fixed site services..
320-190	N/A	Replacement of existing equipment	Replacement of equipment was repealed as a COPN project, section deleted.
320-200	N/A	Coordination of services	Philosophical statement deleted; not measurable or verifiable during the project review process.
320-210	230-50	Cost	All “cost” sections were duplicative and redundant; sections were combined to facilitate use of the SMFP.
320-220	230-180	Staffing	Section revised; language updated and ambiguities removed.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
320-230	230-190	Space	Section revised; language updated and ambiguities removed.
320-240 Magnetic Resource Imaging (MSI)	230-200	Policy for the development of MSI services	Statement retained to provide guidance regarding magnetic resource imaging.
320-250	N/A	Potential clinical applications of MSI Technology	Statement of philosophy, not measurable, section deleted.
320-260	N/A	MSI technology described	Statement of philosophy, not measurable, section deleted.
320-270 Positron Emission Tomography (PET)	N/A	Consumer acceptance of services offered	Statement of philosophy, not measurable, section deleted.
320-280	230-210	Service area	Section revised; language updated and ambiguities removed.
320-290	N/A	Hours of operation	Section deleted, not measurable or verifiable during the project review process.
320-300	N/A	Location of services	Combine with section 210
320-310	320-220	Service capability	Section revised; language updated and ambiguities removed.
320-320	N/A	Projecting demand for service	Philosophical statement deleted; not measurable or verifiable during the project review process.
320-330	N/A	Minimum utilization	Capacity volumes adjusted to reflect national standards and moved to new section 220
320-340	230-230	Additional scanners	Section revised; language updated and ambiguities removed.
320-350	N/A	Replacement of service	Replacement of equipment was repealed as a COPN project, section deleted.
320-360	N/A	Coordination of services	Section no longer a relative consideration for project review.
320-370	230-50, 60	Less costly alternatives	All "cost" sections were duplicative and redundant; sections were combined to facilitate use of the SMFP.
320-380	230-60	Financial access	Section was duplicative and redundant; combined to facilitate use of the SMFP.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
320-390	230-240	Staffing	Section revised; language updated and ambiguities removed.
320-400 Single Photon Emission Computed Tomography (SPECT)	N/A	Consumer acceptance of service offered	Section deleted, criteria not measurable or verifiable during the project review process.
320-410	230-250 Non-cardiac Nuclear Imaging	Location	Category name changed as a result of change in COPN law. Section revised; language updated and ambiguities removed.
320-420	230-60	Financial considerations; ability to pay	Section was duplicative and redundant; sections were combined to facilitate use of the SMFP.
320-430	230-260	Introduction of SPECT as a new service	Section revised; language updated and ambiguities removed.
320-440	N/A	Additional scanners	Combined with new section 260
320-450	N/A	Replacement of existing equipment	Replacement of equipment repealed as a reviewable project, section deleted.
320-460	230-50	Comparability of charges	Section was duplicative and redundant; sections were combined to facilitate use of the SMFP.
320-470	230-270	Medical Director	Section revised; language updated and ambiguities removed.
320-480	N/A	Additional staff	Not reviewable for granting a COPN, Licensure criteria.
330-20 Lithotripsy Services	N/A	Acceptability; waiting time; consumer participation	Philosophical statement deleted; not measurable or verifiable during the project review process.
330-30	230-480	Accessibility; financial considerations	Section was duplicative and redundant; sections were combined to facilitate use of the SMFP.
330-40	230-490	Availability; need for new services; expanded or replaced.	Section revised; language updated and ambiguities removed.
330-50	N/A	Continuity; coordination of services	Philosophical statement deleted; not measurable or verifiable during the project review process.
330-60	230-50	Cost comparability	All "cost" sections were duplicative and redundant; sections were combined to facilitate use of the SMFP.
330-70	N/A	Quality; staffing	Section revised; language updated and

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
			ambiguities removed.
340-20 Radiation Therapy Services	N/A	Acceptability; consumer participation	Philosophical statement deleted; not measurable or verifiable during the project review process.
340-30	230-280, 60	Accessibility; time; financial considerations	Section revised; language updated and ambiguities removed.
340-40	230-290	Availability; need for new service; expanded; replacement of service	Section revised; language updated and ambiguities removed.
340-50	230-300	Continuity; tumor registry; discharge and follow-up care	Section revised; language updated and ambiguities removed.
340-60	230-50	Cost; cost comparability	All “cost” sections were duplicative and redundant; sections were combined to facilitate use of the SMFP.
340-70	230-310, 320	Quality; staffing; financial considerations; patient care; support; care.	Section revised; language updated and ambiguities removed.
340-80 Gamma Knife Surgery	N/A	Accessibility; travel time; financial considerations	Philosophical statement deleted; not measurable or verifiable during the project review process.
340-90	230-330 Stereotactic Radiosurgery	Availability; need for new service	“Gamma Knife” is a trademark name, therefore, name of subsection change to reflect category of equipment.
340-100	230-340	Continuity; coordination of services; tumors registry; discharge and follow-up	Section revised; language updated and ambiguities removed.
340-110	230-50, 60	Cost comparability	All “cost” sections were duplicative and redundant; sections were combined to facilitate use of the SMFP.
340-120	230-350	Quality; staffing; equipment	Section revised; language updated and ambiguities removed.
350-10 Miscellaneous Capital Expenses	230-530	Purpose	Language updated.
350-20	230-540	Project need	Language updated.
350-30	230-550	Facilities expansion	Language updated
350-40	230-560	Renovation or modernization	Language updated.
350-50	230-570	Equipment	Language updated.
350-60	N/A	Assurances	Section invalid, deleted.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
360-20 Nursing Home Services	N/A	Acceptability	Philosophical statement deleted; not measurable or verifiable during the project review process.
360-30	230-460	Accessibility	Section revised; language updated and ambiguities removed.
360-40	230-470	Availability	Section revised; language updated and ambiguities removed.
360-50	N/A	Continuity	Philosophical statement deleted; not measurable or verifiable during the project review process.
360-60	230-50, 60	Costs	All “cost” sections were duplicative and redundant; sections were combined to facilitate use of the SMFP.
360-70	N/A	Quality	Philosophical statement deleted; not measurable or verifiable during the project review process.